

Claims **2, 4, 12, 25-28 and 31** have been cancelled, claims **1, 3, 7, 8, 10, 21, 23, 24, 29 and 32** have been amended, the Abstract has been amended as requested, the disclosure has been amended at pages 7, 17 and 18, and no new claims have been added as per the amendment filed August 22, 2011. No additional or supplemental Information Disclosure Statements (IDSs) have been filed as of the date of this Office action.

Claims **1, 3, 5-11, 13-24, 29, 30 and 32** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line **y**, the line number “**y**” is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

The disclosure is objected to because of the following informalities:

In the second paragraph of page 18, lines 2-6, the description of how automated equipment clogging has been avoided is unclear and needs to be amended to insure that the meaning intended is readily understood.

Appropriate correction is required.

Applicant’s arguments filed August 22, 2011 have been fully considered but they are not persuasive.

The changes made by amendment are noted with appreciation. However, the above noted paragraph at page 18 continues to be in need of clarification.

35 U.S.C. §101 reads as follows:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”

Claim **29** (two occurrences) and claim **30**(2 occurrences) are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See for example *Ex parte Dunki*, 153 USPQ 678

(Bd. App. ,1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

In claims **29** and **30** the term “use” (all occurrences) occurring within the term “ready-for-use” is a derivative of the verb -- to use --, and in view of the above judicial guidance, examiner respectfully suggests that said term should be replaced with alternative terminology not derived from the noted verb.

Applicant’s arguments filed August 22, 2011 have been fully considered but they are not persuasive.

The amendments made are noted with appreciation. *In re* the term “ready-to-use” at lines 5 and 11 of claim **29**, examiner again refers to the above judicial guidance, and respectfully suggests that the noted terms might be deleted in favor of the term -- ready for application -- or the like as one way to effectively address the instant issue. See also claim **30** at lines 5 and 7 wherein the same issue reoccurs and wherein the same suggested solution would also be effective if adopted.

Claims **1, 3, 5-11, 13-24, 29, 30 and 32** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Factors to consider in this analysis:

a) Actual Reduction to Practice? The instant disclosure has only exemplified processes wherein the isolation of “DNA” has been demonstrated. The specific embodiments have not described how to isolate all species encompassed by the generic terms “RNA” and “hybrid molecules or RNA and DNA,”

b) Disclosure of Drawings or Structural Chemical Formulas? This factor is not relevant to this particular analysis.

c) Sufficient relevant identifying characteristics? This factor is not relevant to this particular analysis.

d) Method of making the claimed invention? This factor is dealt with in the first paragraph of this analysis.

e) Level of skill in the art? This factor is not relevant to this particular analysis.

f) Predictability in the art? The instant art is highly predictable as revealed by the numerous relevant prior art citations kindly provide by applicant.

For the above stated reasons the instant claims have been found to lack adequate support from the written description.

Applicant's arguments filed August 22, 2011 have been fully considered but they are not persuasive.

The above rejection has been amended to reflect the changes made in the instant claim set by amendment.

Applicant has argued that the limitation of the instant claims as amended to "DNA, RNA and hybrid molecules of RNA and DNA" is sufficient to overcome the above rejection.

Applicant also argues that one of ordinary skill would know how to apply the instant process to isolate either RNA or hybrid molecules of RNA and DNA because of similarities in their properties. Examiner respectfully disagrees, noting that DNA and RNA separations are distinctly different in the prior art, and directs applicant to the amended ground of rejection above wherein the arguments have been amended to reflect the change in the scope of subject matter being claimed. For these reasons the above rejection has been found to remain valid and has therefore been repeated.

Claims 1, 3, 5-11, 13-24, 29, 30 and 32 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for a process for the separation of DNA from various plant sources wherein polyethylene glycol 8000 or a synthetic oligomer equivalent (see "polyvinylpyrrolidone" in Example 2 at page 18) is present as a "hydratable additive," does not reasonably provide enablement for the many different processes possibly necessary to effect the efficient separation of any "RNA" or any "hybrid molecule of RNA and DNA" from any specific source material in the presence of either polyethylene glycol 8000, or any one of the other hydratable additives listed either specifically, or encompassed within a

genus, in either of claim 1 or claim 29. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of “undue experimentation” is appropriate are as follows:

In view of the analysis of the previous rejection wherein many of the Wands factors have already been addressed, this rejection will be limited to a final conclusion concerning the need for undue experimentation.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure has been found to remain excessive because, while the process is now broadly claimed to be effective in the separation/isolation of any “DNA,” “RNA,” or any “hybrid molecule of RNA and DNA” from any source, only DNA isolation from a few plant sources has been enabled by the instant specific embodiments. In addition, the contents of the remainder of the disclosure directed to the instant claimed subject matter appears to be entirely prospective, lending support to the conclusion that the instant disclosure has only enabled a very small fraction of the possible process embodiments encompassed by the generic terms “DNA,” “RNA,” and “hybrid molecules of RNA and DNA.” Examiner respectfully suggests substantial narrowing of the scope of claimed subject matter.

Applicant’s arguments filed August 22, 2011 have been fully considered but they are not persuasive.

Applicant is respectfully referred to the response to applicant’s arguments following the previous rejection because there is no argument made which refers to the above rejection specifically.

Claims 1, 5 and 29 are objected to because of the following informalities:

In claim 1 at line 7 and claim 29 at line 9 the term “Agar-Agar” is improperly capitalized.

In claim **5** the term “siliceous- oxide” apparently includes a typographical error. Did applicant intend the term to read -- siliceous-oxide -- as in claim **32**?

Appropriate correction is required.

Claims **1, 3, 5-11, 13-24, 29, 30 and 32** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **1** at line 7, the term “amylase” is technically erroneous because said term is directed to an enzyme capable of hydrolyzing -- amylose -- (aka “starch”). Did applicant intend the noted term to read -- amylose --? See also claim **29** at line 8 wherein the same issue reoccurs.

Applicant’s arguments with respect to claims **1-32** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant’s amendments.

In claim **1** at lines 20-21, a -- proviso -- has been presented but said proviso does not clearly describe the necessity for the limitation. Examiner respectfully suggests that an amendment of claim **1** at lines 20-21 to read as follows:

-- with the proviso that the concentration of the hydratable additive is selected so that during the separation process no substantial clustering of said magnetic particles occurs in the presence of the hydratable additive modified aqueous solution -- or the like.

Applicant’s arguments with respect to claims **1-32** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant’s amendments.

Claim **13** is now improperly dependent because claim **12** has been cancelled. See also claim **32** wherein a similar issue arises.

Applicant’s arguments with respect to claims **1-32** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant’s amendments.

In claim **30** at lines 2-4, the term “ selected from the group consisting of ... or ” is technically erroneous. Applicant is respectfully reminded that a Markush preamble reads as follows: -- selected from the group consisting of ... and -- (emphasis added).

Applicant’s arguments filed August 22, 2011 have been fully considered but they are not persuasive.

The introduction of various amendments to address rejections under 35 U.S.C. §112, second paragraph, are noted with appreciation. However, the above rejection has been maintained to point out one error which has not yet been corrected.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

“A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.”

Claims 1, 3, 5-11, 13-24, 29, 30 and 32 are rejected under 35 U.S.C. §103(a) as being unpatentable over **Hawkins ‘628** (PTO-1449 ref. AA1: US **5,705,628**) in view of **Smith et al. ‘945** (PTO-892 ref. A: US **6,027,945**).

The instant claims are directed to a process for the isolation of a “biopolymer” (specifically enabled for DNA isolation) wherein silica-coated magnetic particles, a salt plus a polyalkylene glycol “additive” are present during the extraction and adsorption of DNA onto the silica surface of DNA and subsequently conventional steps are applied to wash away impurities and elute the DNA from the adsorbent. The option of automation of the process is also claimed.

Applicant is referred to the abstract of **Hawkins ‘628** wherein nearly all of the elements of the instant claimed isolation process as applied to obtaining DNA have been disclosed including the presence of variably optimizable concentrations of a salt and of a polyethylene glycol in the extraction/adsorption steps. In addition at column 2, lines 10-12, the potential for automation of the claimed process is also specifically disclosed.

Hawkins '628 does not expressly disclose a silica coated magnetic particle as the adsorbent to which the DNA is adsorbed.

Smith et al. '945 discloses a silica-coated magnetic particle as the adsorbent to which the DNA is adsorbed as part of a DNA purification protocol similar to that of **Hawkins '628**.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the silica-coated magnetic particles of **Smith et al. '945** for the carboxyl-coated magnetic particles of **Hawkins '628** in the course of routine experimentation to optimize the process disclosed by **Hawkins '628**.

One having ordinary skill in the art would have been motivated to combine these references because both the primary and secondary references are directed to similar protocols for the isolation of DNA from cellular sources, and which the disclosed methods share several common process elements.

Therefore, the instant claimed process for the isolation and purification of DNA from a cellular source by a process that relies on silica-coated magnetic particles and may be optimized by variations in the concentrations of salt and a polyalkylene glycol would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

Applicant's arguments filed August 22, 2011 have been fully considered but they are not persuasive.

Applicant has argued that the clumping of silica-coated magnetic beads during a DNA separation protocol was a well recognized in the art problem which the instant claimed process has effectively solved. While this may be correct, examiner is presently not aware of where within the instant file history this fact has been established with accompanying references to establish that this difficulty is a recognized problem in the execution of similar DNA separations, separation which presumably rely on silica-coated magnetic particles. Examiner respectfully suggests that applicant's argument would be greatly assisted and supported by adding to the instant record any references citable in support of applicant's assertion. In the absence of such a showing, and in view of applicant's arguments in support of a finding of patentability, it is examiner's conclusion that the instant claimed process is not presently

patentably distinguishable from the above cited prior art references, but that disclosures of the kind hinted at by applicant's arguments may tip the balance in applicant's favor.

In addition examiner respectfully suggests that the instant claimed process may be claimed alternatively with the Jepson format: e.g.

-- [prior art process(es) disclosed] wherein the improvement comprises [the improvement disclosed] --. See the MPEP at §2129 for additional guidance and commentary on the Jepson claim format.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <<http://pair-direct.uspto.gov>>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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10/29/2011

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